

From the INTERNATIONAL BUREAU

PCT**NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)**

(PCT Rule 44bis.1(c))

To:

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Date of mailing (*day/month/year*)

28 January 2010 (28.01.2010)

Applicant's or agent's file reference

10527-830WO1

IMPORTANT NOTICE

International application No.

PCT/US2008/069544

International filing date (*day/month/year*)

09 July 2008 (09.07.2008)

Priority date (*day/month/year*)

13 July 2007 (13.07.2007)

Applicant

BOSTON SCIENTIFIC LIMITED et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| | | |
|--|--|--|
| Applicant's or agent's file reference 10527-830WO1 | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/US2008/069544 | International filing date (<i>day/month/year</i>) 09 July 2008 (09.07.2008) | Priority date (<i>day/month/year</i>) 13 July 2007 (13.07.2007) |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | |
| Applicant BOSTON SCIENTIFIC LIMITED | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Date of issuance of this report 19 January 2010 (19.01.2010) Authorized officer <p style="text-align: center; font-weight: bold;">Athina Nickitas-Etienne</p> e-mail: pt04.pct@wipo.int |
|---|--|

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2008/069544

International filing date (day/month/year)
09.07.2008

Priority date (day/month/year)
13.07.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61L31/02 A61L31/14 A61L31/12 A61L31/18

Applicant
BOSTON SCIENTIFIC SCIMED, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/069544

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/069544

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-------------------|
| Novelty (N) | Yes: Claims | <u>10-21</u> |
| | No: Claims | <u>1-9, 22-33</u> |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | <u>1-33</u> |
| Industrial applicability (IA) | Yes: Claims | <u>1-33</u> |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Cited documents

Reference is made to the following documents:

- D1 WO 2004/108021 A2 (SDGI HOLDINGS INC [US]; ISTEPHANOUS NAIM [US]; MARIK GREG C [US]; LESS) 16 December 2004 (2004-12-16)
- D2 US 2004/187980 A1 (JUNG JIN-WON [US] ET AL) 30 September 2004 (2004-09-30)

2. Novelty

The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claims 1-9 and 22-33 is not new.

D1 discloses implantable medical devices such as stents, implantable tubes, catheter tips... (see page 7, line 14-24) at least partially formed from a metal matrix composite that provides a metal matrix and a reinforcing component interspersed within the metal matrix (see page 20, line 21-30). The reinforcing component includes metal borides such as Ti B₂ (see page 21, line 14-19).

Therefore, the subject-matter of claims 1-9, 22-33 is not new over D1 according to Article 33(2) PCT.

D2 discloses high-strength, low hysteresis shape memory alloys (SMAs) and, in particular TiNi-based SMAs, employing coherent low-misfit nanoscale size precipitates (see page 2, paragraph 13) which can be used in self-expanding medical stents (see page 5, paragraph 64). To improve ductility of the material the grain size has to be reduced, and for this purpose Boron is preferably added to form borides (see page 4, paragraph 52).

Therefore, the subject-matter of claims 1-9, 22, 29-30 is not new over D2 according to Article 33(2) PCT.

3. Inventive step

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claims 1-33 does not involve an inventive step.

As the subject-matter of claims 1-9 and 22-33 is not new it cannot be considered as involving an inventive step (Article 33(3) PCT).

D1 is regarded as being the closest prior art. It discloses implantable medical devices such as stents, implantable tubes, catheter tips... (see page 7, line 14-24) at least partially formed from a metal matrix composite that provides a metal matrix and a reinforcing component interspersed within the metal matrix (see page 20, line 21-30). The reinforcing component includes metal borides such as $Ti B_2$ (see page 21, line 14-19).

The subject-matter of claims 10-21 therefore differs from this known D1 in the size of the boride intermetallic phases and in different physical properties of the alloy.

The problem to be solved by the present invention may therefore be regarded as the provision of alternative endoprosthesis with increased elastic modulus and better recoil performance.

The solution proposed in claims 10-21 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The features in claims 10-21 are merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

Thus, the subject-matter of claims 10-21 does not fulfill the requirements of Article 33 (3) PCT.